International Journal of Medicine and Pharmaceutical Research
E-ISSN: 2321-2624 | https://doi.org/10.30904/j.ijmpr.2026.5041

An Analysis of Medical Device Regulatory Pathways: A Comparison between USFDA, EU-MDR, and Indian CDSCO Guidelines

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Received: 21-03-2026 | Revised: 28-04-2026 | Accepted: 18-05-2026 | Published: 30-06-2026

ABSTRACT:
The aim of this research is to produce a rigorous, practice-oriented comparative analysis of medical device regulatory pathways in the United States, European Union, and India. The study seeks to generate actionable recommendations, templates, and comparative models that can guide manufacturers, regulators, and policymakers in navigating multi-jurisdictional submissions efficiently while maintaining high standards of safety, quality, and transparency. This work set out to provide a comparative analysis of medical device regulatory pathways in the United States (USFDA), the European Union (EU MDR), and India (CDSCO). By systematically examining classification systems, pre-market approval routes, dossier requirements, quality system obligations, UDI traceability, and post-market surveillance, the study has produced a structured view of both convergence trends and divergences with practical consequences. The study acknowledges that jurisdictional guidance is continuously evolving, and that timelines vary by product complexity, dossier quality, and regulatory interactions. Thus, while the comparative framework is robust as of September 2025, it requires ongoing monitoring.
Keywords: USFDA, European Union, UDI traceability, CDSCO, regulatory interactions

Introduction

Global Importance of Medical Device Regulation [1-4].

Medical devices are essential in modern healthcare, spanning simple consumables such as bandages and thermometers to complex, software-driven technologies like pacemakers, robotic surgical systems, and artificial intelligence–enabled diagnostic tools. The global medical device market is projected to exceed USD 800 billion by 2030, with double-digit growth in segments like digital health, wearable sensors, and minimally invasive surgical equipment. Regulatory oversight is critical to balance innovation, market access, and patient safety. Unlike pharmaceuticals, medical devices are highly diverse in design, mechanism of action, and clinical application, which necessitates **risk-based regulation** rather than one-size-fits-all rules.

Historical Evolution of Regulatory Frameworks [5, 6]

The United States pioneered comprehensive device regulation through the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act. These established classification into Classes I–III, the 510(k) premarket notification process, and the premarket approval (PMA) route for high-risk devices. Over time, specialized pathways such as the De Novo classification and breakthrough device designation were added, reflecting the need for flexibility. The European Union initially regulated devices under the Medical Device Directives (MDDs), but widespread criticism following device-related scandals (e.g., PIP breast implants) led to the more stringent EU Medical Device Regulation (MDR) 2017/745. The MDR introduced stricter clinical evaluation, lifecycle post-market surveillance (PMS), and greater accountability for manufacturers and Notified Bodies.

India, historically regulating devices as "drugs" under the Drugs and Cosmetics Act, enacted the Medical Devices Rules (MDR) 2017 to create a dedicated, risk-based classification system (Classes A–D). The Central Drugs Standard Control Organization (CDSCO) now oversees licensing, manufacturing, import, and vigilance under the Materiovigilance Programme of India (MvPI).

Methodology

Study Design

This research employs a qualitative comparative policy analysis (CPA) design, a methodological framework particularly well-suited for examining regulatory regimes that are both heterogeneous in formulation yet convergent in purpose. The comparative lens enables a systematic exploration of how distinct jurisdictions articulate, implement, and enforce medical product regulations while highlighting shared principles and divergences in emphasis.

The rationale for adopting a qualitative approach lies in its ability to capture the interpretive and contextual nuances of regulatory texts and institutional practices, rather than reducing them to purely quantitative indicators. By engaging with legal instruments, institutional outputs, and scholarly assessments, the study develops a multi-layered perspective that integrates doctrinal analysis with policy evaluation. To enhance validity and minimize bias, the design incorporates methodological triangulation, drawing upon three complementary categories of data sources:

Primary legal and regulatory texts

These include binding statutory and regulatory instruments that constitute the legal backbone of medical product oversight. Examples encompass Title 21 of the U.S. Code of Federal Regulations (21 CFR) for the FDA framework, the European Union Medical Device Regulation (EU MDR 2017/745), and the Medical Device Rules (MDR 2017) in India. Analyzing these instruments provides a direct understanding of codified requirements, legal definitions, and compliance expectations across jurisdictions.

1. **Competent authority publications**
   Outputs from national and supranational regulatory authorities form the second data stream. This includes FDA databases and enforcement reports, European Commission and Directorate-General for Health and Food Safety (DG SANTE) portals, and Central Drugs Standard Control Organization (CDSCO) circulars and Indian Pharmacopoeia Commission (IPC) notifications. These materials illustrate how regulations are operationalized, interpreted, and periodically updated in practice, thereby linking textual mandates with institutional enforcement dynamics.
2. **High-credibility secondary analyses**
   The third category consists of peer-reviewed journal articles, white papers from recognized think-tanks, and sectoral surveys conducted by professional associations. These sources offer critical, often comparative, insights into regulatory performance, highlight implementation challenges, and contextualize the frameworks within broader global debates on safety, efficacy, innovation, and access.

The integration of these three data categories ensures a comprehensive, evidence-based assessment. The study not only identifies convergences and divergences in regulatory frameworks but also situates them within the evolving global landscape of pharmaceutical and medical device governance.

Triangulation ensures validity and mitigates bias from relying on a single source type. The outputs include:

- **Structured comparative matrices** to display classification, QMS, PMS, and dossier requirements.
- **"Like-for-like" mapping tables** aligning US, EU, and Indian terminologies.
- **Decision trees** illustrating practical submission sequencing and bottlenecks.

Table 1: Data Source Categories

Source Type	Examples	Rationale
Primary legal texts	21 CFR, EU MDR, India MDR 2017	Binding instruments; core evidence base
Authority portals	FDA GUDID, EC MDR page, CDSCO/IPC	Up-to-date official implementations
Guidance documents	FDA guidance, MDCG documents	Clarify regulatory expectations
Secondary analyses	Peer-reviewed papers, sector surveys	Operational insights; triangulation

Data Sources

Data were systematically gathered from multiple domains:

- **Primary Legal/Regulatory Texts:**
  - **US:** Title 21 CFR, including Parts 803 (MDR), 807 (510(k)), 812 (IDE), 814 (PMA), 820 (QMSR).
  - **EU:** Regulation (EU) 2017/745 (MDR), especially Annex II–III (technical documentation/PMS) and Annex IX–XI (conformity assessment).

India: Medical Devices Rules (MDR) 2017 (effective 2018), with amendments and classification lists.

Competent Authority Portals:

US **FDA** databases (Product Classification, GUDID, 510(k)/PMA databases).

European Commission MDR page, MDCG guidance library, EUDAMED documentation.

CDSCO/IPC portals including SUGAM/MD-Online and Materiovigilance Programme of India (MvPI).

Guidance & Authoritative Documents:

FDA Guidance (510(k), De Novo, PMA, Breakthrough, STeP, SaMD).

MDCG Documents (clinical evaluation, SSCP, PMCF, PRRC, vigilance).

ISO standards, especially ISO 13485:2016.

Secondary Literature (selective use):

- Peer-reviewed comparative studies.
- White papers on NB capacity, MDUFA timelines, CDSCO implementation.

Table 2: Inclusion vs. Exclusion Criteria

Included if…	Excluded if…
Official or peer-reviewed	Outdated directives (MDD/AIMDD) unless transitional
Directly covers classification, pathways, QMS, UDI, PMS	Opinion/commentary without authority
Current (valid as of Sept 2025)	Commercial/taxation/pricing sources

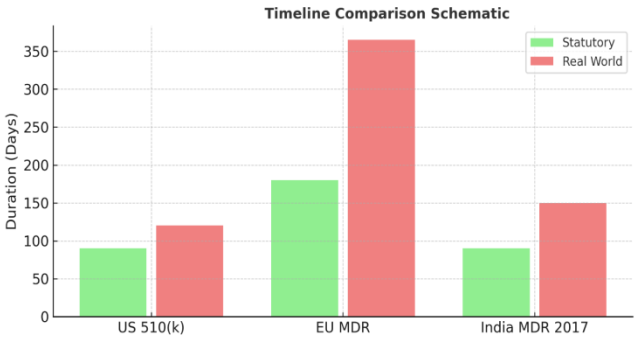

Fig.1: Timeline comparision schematic

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Official sources or peer-reviewed publications.
- Direct relevance to **classification/pathways, dossier content, QMS, UDI/traceability, PMS/vigilance.**
- Validity as of **September 2025.**

Exclusion Criteria:

- Outdated directives (MDD/AIMDD) unless used for transition context.
- Non-peer-reviewed commentaries lacking official verification.
- Non-regulatory commercial sources (pricing, reimbursement, customs).

Analytic Approach

The analysis follows four systematic steps:

Thematic Coding by Lifecycle Stage.

Obligations were coded into **pre-market, market access, and post-market** categories. For instance, bench/preclinical testing codes were grouped as pre-market, while PMSR/PSUR reporting was coded as post-market.

Cross-Jurisdictional Mapping

Terminologies were harmonized to enable comparison. For example:

- **US Class II ↔ EU Class IIa/IIb ↔ India Class B/C**.
- **510(k) ↔ EU Technical Documentation (Annex II/III) ↔ India DMF/PMF**.

Risk/Timeline Assessment.

Comparative timelines were analyzed: statutory review clocks (e.g., 90 FDA days for 510(k)) vs. real-world durations (often longer under EU MDR due to NB capacity). Bottlenecks such as predicate availability, NB review slots, and CDSCO classification queries were identified.

Sensitivity Analysis.

Particular focus was given to **digital health/SaMD and implantables**, where regulatory expectations diverge more strongly. AI/ML governance, cybersecurity, and PMCF/registries were emphasized.

Quality Assurance:

To ensure the reliability, validity, and transparency of findings, the study incorporated multiple quality assurance measures throughout the research process. These measures were deliberately designed to minimize interpretive bias, enhance reproducibility, and align the analysis with established standards of qualitative policy research.

Dual Source Verification

Each regulatory requirement or interpretive claim was validated through at least two independent sources. For instance, a provision from the U.S. Code of Federal Regulations (CFR) was cross-checked against the corresponding FDA guidance document or compliance manual, while an EU MDR requirement was triangulated with European Commission explanatory notes or MDCG guidance documents. This dual verification reduced the risk of relying on a single authoritative text and ensured consistency between codified law and its practical application.

Consistency Checks

Findings were further strengthened by cross-verification against dynamic resources, such as official FAQs, public notices, and updated regulatory portals. This was particularly important in rapidly evolving regulatory environments—such as medical device Unique Device Identification (UDI) systems—where guidance is frequently updated. These checks ensured that interpretations remained aligned with the most current regulatory positions.

Conservative Interpretation

In cases where ambiguity or uncertainty arose, the analysis deliberately employed a conservative, regulator-aligned interpretive stance. For example, where the CDSCO UDI implementation timelines presented evolving requirements, the study adopted the strictest interpretation that would be least likely to underestimate compliance obligations. This approach enhanced the study's practical utility for stakeholders while preventing overextension of claims.

Documentation and Audit Trail

To maintain transparency and traceability, a detailed documentation system was employed. All coding decisions, thematic categorizations, cross-jurisdictional mappings, and draft comparative matrices were systematically archived. This audit trail ensures that every analytical step can be revisited, scrutinized, and independently validated by future researchers or reviewers, thereby reinforcing methodological integrity. Collectively, these measures establish a robust framework of quality assurance. By integrating verification, consistency, conservatism, and transparency, the study ensures that its conclusions are not only academically rigorous but also credible and applicable to regulatory practice.

Results and Discussion

Risk Classification Summary

Across the three jurisdictions, **risk classification** forms the foundation of medical device regulation.

- **USFDA** uses a **three-class system (I–III)**, determined by intended use, indications, and risk controls. **Class II** devices rely on substantial equivalence (SE) to predicates, while **Class III** devices generally require PMA.
- **EU MDR** applies a **rule-based system (22 rules in Annex VIII)**, stratifying devices into **Class I (Is, Im, Ir), IIa, IIb, and III**, with invasiveness, duration of contact, implants, and software being key criteria.
- **India (CDSCO)** under **MDR 2017** applies a **four-class system (A–D)**, with **A lowest and D highest risk**, incorporating specific IVD classification rules.

A key observation is that **software classification diverges**: EU uses rule-based (Rule 11), US applies a risk + enforcement discretion model, and India aligns progressively with IMDRF.

Table 3: Risk Classification Systems

Jurisdiction	Classes	Basis
USFDA	I, II, III	Intended use, indications, risk controls; SE for Class II; PMA for Class III
EU MDR	I (Is/Im/Ir), IIa, IIb, III	22 classification rules: invasiveness, duration, implants, software
India CDSCO	A, B, C, D	Risk-based; A lowest, D highest; separate IVD classification criteria

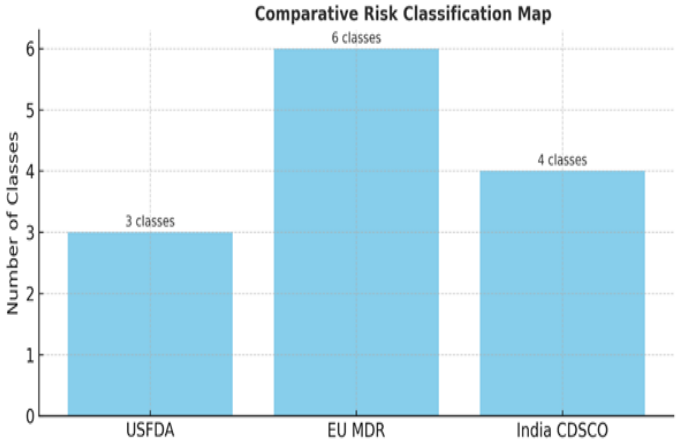

Fig.2: Comparative Risk classification system

Pre-Market Pathways Overview

The comparative analysis of pre-market regulatory pathways demonstrates that while jurisdictions differ in terminology, procedural structures, and institutional arrangements, they converge on a risk-based and evidence-driven paradigm designed to ensure the safety, efficacy, and quality of medical devices prior to market entry. The findings highlight that all three systems—the U.S. Food and Drug Administration (USFDA), the European Union under the Medical Device Regulation (EU MDR 2017/745), and India under MDR 2017—rely on tiered risk classification, proportional evidentiary requirements, and oversight by either a regulator or an accredited Notified Body (NB).

United States (USFDA)

The U.S. regulatory landscape is characterized by three primary pre-market pathways:

- **510(k) Premarket Notification:** Predominantly used for moderate-risk devices, the 510(k) pathway requires manufacturers to demonstrate *substantial equivalence* to a legally marketed predicate device. This pathway supports quicker market access but relies heavily on comparative, rather than de novo, evidence.
- **De Novo Classification:** Designed for novel, low-to-moderate risk devices without predicates, the De Novo process balances innovation and risk management by requiring sufficient evidence of safety and effectiveness while avoiding the full PMA burden.
- **Premarket Approval (PMA):** Reserved for high-risk Class III devices, PMA involves extensive clinical evidence, manufacturing inspections, and rigorous FDA review. The pathway is resource-intensive but provides the highest assurance of safety and performance.

The USFDA system is underpinned by statutory performance goals (e.g., MDUFA targets), ensuring predictable timelines. This results-oriented approach aligns with industry needs for regulatory certainty, while maintaining a high evidentiary threshold for high-risk products.

European Union (EU MDR 2017/745)

The EU MDR establishes a Notified Body-led conformity assessment framework, where market access is contingent upon demonstrating compliance with essential safety and performance requirements. Key features include:

- **Risk-Based Conformity Assessments:** With the exception of most Class I devices, which rely on self-certification, higher-risk devices must undergo third-party assessment by a designated Notified Body.
- **Technical Documentation Review:** CE marking follows a detailed review of clinical evaluation reports, risk management files, and post-market surveillance planning.
- **Centralized Oversight with Decentralized Execution:** While the European Commission provides overarching regulation, NBs function as delegated assessors, creating variability in assessment stringency but also allowing distributed capacity.

Compared to the USFDA, the EU system places greater emphasis on continuous clinical evaluation and lifecycle documentation, thereby embedding post-market obligations into the pre-market approval logic.

India (MDR 2017)

India's framework under the Medical Device Rules, 2017 introduces a tiered licensing system administered by the Central Licensing Authority (CLA) and State Licensing **Authorities (SLAs)**:

- **Class A devices** (low-risk) are licensed by SLAs with minimal third-party oversight.
- **Classes B, C, and D** require involvement of accredited Notified Bodies for audits, with the CLA retaining approval authority for higher-risk categories.
- **Structured Licensing Forms:** Market access requires compliance with prescribed forms (e.g., MD-5 to MD-10 for registration and MD-14/15 for manufacturing/import licensing), creating a standardized documentation process.

India's approach reflects a hybrid adoption of U.S. and EU principles, embedding risk-stratified oversight, NB audits, and centralized licensing into a framework that is still maturing in terms of enforcement capacity and international recognition.

Comparative Discussion

Despite differences in regulatory architecture and institutional traditions, convergence emerges across jurisdictions on three principles:

1. **Risk-Based Stratification:** Device classification dictates the depth of pre-market scrutiny—ranging from streamlined notifications for low-risk devices to exhaustive clinical evidence for high-risk innovations.
2. **Evidence-Driven Market Entry:** Whether through substantial equivalence (USFDA 510(k)), continuous clinical evaluation (EU MDR), or CLA/NB-mediated audits (India), pre-market approval universally relies on demonstrable safety and performance data.
3. **Institutional Mediation:** Regulators (USFDA, CLA) or Notified Bodies (EU, India) act as gatekeepers, ensuring independent validation prior to market entry.

The analysis also reveals systemic divergences. The USFDA provides the most centralized and predictable timelines, supported by statutory goals. The EU MDR emphasizes holistic lifecycle management, embedding pre- and post-market obligations into a single continuum. India's MDR 2017 represents an emerging hybrid system, balancing harmonization with global practices and the realities of a developing regulatory infrastructure.

Ultimately, the results underscore that pre-market pathways, while linguistically and procedurally distinct, embody a shared philosophy of proportional oversight. This alignment facilitates international dialogue on regulatory convergence, though challenges remain in mutual recognition and capacity building.

QMS: Convergence and Differences

- US: QMSR (21 CFR 820) aligns with ISO 13485, enforceable Feb 2026; FDA-specific elements remain (complaints, records).
- EU: MDR Article 10 mandates lifecycle QMS; NB audits; role of PRRC; defined obligations for economic operators.
- India: ISO 13485 certification central to licensing (Classes B–D); CLA/SLA and NB inspections enforce compliance.

UDI and Traceability Snapshot

- US: UDI labeling, DI to GUDID; issuing agencies GS1, HIBCC, ICCBBA.
- EU: UDI system embedded in EUDAMED; device module, Basic UDI-DI concept.
- India: MDR 2017 mandates UDI with staged rollouts; alignment with IMDRF/GS1 underway.

Post-Market Surveillance & Vigilance

- US: 21 CFR 803 MDR reporting; eMDR; corrections/removals; PMA post-approval studies.
- EU: PMS plan (Art. 84), PMSR/PSUR, PMCF, vigilance via EUDAMED.
- India: MvPI adverse event reporting; CDSCO notices; PMS evolving.

Timelines & Operational Considerations

Narrative

Statutory clocks often underestimate real-world durations due to review cycles, NB capacity, or sponsor readiness.

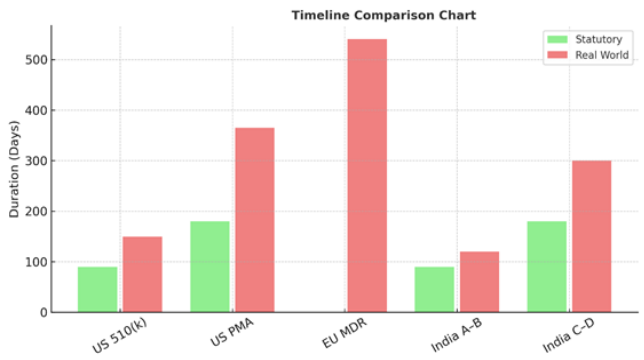

Fig.3: Timeline comparision chart

Discussion

Convergence Trends

The comparative analysis highlights a strong trajectory of convergence across global medical device regulatory frameworks.

Quality Management Systems (QMS).

All three jurisdictions are aligning around ISO 13485:2016 as the baseline QMS framework. The US transition from QSR to QMSR (effective 2026) eliminates many redundancies for multi-region manufacturers, while the EU and India explicitly require ISO 13485 certification as part of conformity assessment or licensing.

UDI and Traceability.

Each system is embedding UDI requirements into regulatory infrastructure:

- US: GUDID fully operational.
- EU: EUDAMED modules, including device and UDI registration, being phased in.
- India: MDR 2017 amendments progressively adopting UDI aligned with IMDRF/GS1.

Lifecycle Oversight.

Regulatory frameworks increasingly depend on post-market surveillance (PMS) and real-world evidence (RWE) to complement premarket data. Both the EU MDR (through PMSR/PSUR/PMCF) and FDA (through eMDR, post-approval studies) reflect a lifecycle regulatory paradigm now echoed in India's MvPI.

Risk-Proportionate Pathways.

All jurisdictions employ risk stratification, with clinical evidence scaled to device risk and novelty. For example, EU MDR mandates more rigorous clinical evaluations for Class IIb/III devices, while US De Novo provides a pathway for novel moderate-risk technologies.

With Practical Impact

Despite convergence, practical divergences persist that influence strategic planning.

US vs EU

- Predicate-driven vs CER/PMCF model. US 510(k) depends on substantial equivalence, which reduces upfront clinical evidence requirements for many moderate-risk devices. EU MDR, by contrast, requires a Clinical Evaluation Report (CER), supplemented by Post-Market Clinical Follow-Up (PMCF), even for devices with existing analogues.
- Novel devices. The US De Novo pathway provides a flexible, risk-tailored entry route; the EU lacks an equivalent and often defaults novel devices into higher scrutiny.

EU vs India.

- Economic operator regime. EU mandates a Person Responsible for Regulatory Compliance (PRRC) and prescribes clear roles for importers, distributors, and authorized representatives. India's MDR 2017 has a simpler framework, but guidance and vigilance tools are expanding (e.g., MvPI).
- Notified Body infrastructure. EU NBs carry significant authority under MDR, while India's NB system is still maturing, with SLA/CLA oversight predominating.

US vs India.

Regulatory predictability. US programs operate within statutory clocks (e.g., 90 FDA days for 510(k)), supported by initiatives such as Breakthrough and STeP. India lacks equivalent statutory timelines, with real-world reviews varying by product and agency resources.

6.3 Strategic Recommendations for Global Submissions

The findings suggest six key strategies for manufacturers pursuing multi-region submissions:

1. **Early Classification Alignment.**
   Confirm device class under US, EU, and Indian frameworks at the earliest stage, with particular attention to software/active devices, where criteria diverge (e.g., EU Rule 11).
2. **Evidence Ladder Planning.**
   Design an integrated bench → preclinical → clinical package that can be modularized across pathways.

Consider FDA's focus on human factors and cybersecurity, EU's requirements for CER/PMCF, and India's risk-based CI permissions.

3. **QMS Readiness.**
   Align internal systems to ISO 13485 with FDA deltas (complaint handling, recordkeeping) in preparation for QMSR 2026. Ensure supplier audits meet EU MDR Annex III and India's licensing expectations.
4. **Documentation Crosswalk.**
   Maintain a **living cross-reference** linking design history file (DHF) content to:
   - FDA 510(k)/PMA submission modules,
   - EU MDR Annex II/III Technical Documentation,
   - India DMF/PMF. This reduces duplication and ensures harmonized dossier updates.
5. **UDI/EUDAMED Data Governance.**
   Invest early in master data governance to populate both GUDID and EUDAMED. Alignment with GS1 standards facilitates scalability and prepares for India's phased UDI adoption.
6. **Resource Buffering.**
   Build conservative resource buffers for EU NB scheduling (often 12–24 months) and India site audits, and establish a rapid-response regulatory team to address authority queries.

Table 5.2 – Pre-Market Pathways

Topic	USFDA	EU MDR	India CDSCO
Primary Pathways	510(k), De Novo, PMA	NB conformity assessment (Annex IX–XI) → CE	CLA/SLA licensing; DMF/PMF; NB audits (B–D)
Clinical Investigations	IDE (21 CFR 812)	Arts. 62–82; Annex XV; SSCP for Class III/implants	MD-22/23 permissions
Performance Goals	510(k): 90 FDA days; PMA: 180 days (statutory)	No statutory clock; NB capacity-dependent	SLA/CLA windows; 3–12+ months practical

Table 5.3 – Dossier Crosswalk

Component	US (510(k)/De Novo/PMA)	EU (Annex II/III TD)	India (DMF/PMF)
Device Description	✓	✓	✓
Risk Management (ISO 14971)	✓	✓	✓
Bench/Preclinical Testing	✓	✓	✓
Clinical Evaluation	510(k): literature/special controls; De Novo/PMA: stronger	CER; PMCF plan	Clinical data; CI permissions
Labeling/UDI	FDA labeling + GUDID	MDR labeling + EUDAMED	MDR 2017 labeling; UDI evolving
QMS Evidence	QMSR/ISO 13485 + supplier controls	NB audit ISO 13485 + MDR	ISO 13485 cert.; site audits

Conclusion

This work set out to provide a comparative analysis of medical device regulatory pathways in the United States (USFDA), the European Union (EU MDR), and India (CDSCO). By systematically examining classification systems, pre-market approval routes, dossier requirements, quality system obligations, UDI traceability, and post-market surveillance, the study has produced a structured view of both convergence trends and divergences with practical consequences.

Findings

Convergence

All three systems are gravitating toward a risk-based lifecycle approach anchored in ISO 13485-aligned QMS, unique device identification (UDI) frameworks, and increasing reliance on post-market surveillance and real-world evidence.

Divergences

- US vs EU: Predicate-based 510(k) contrasts with the EU's CER/PMCF model, while the De Novo pathway has no direct EU equivalent.
- EU vs India: The EU mandates PRRC and prescriptive economic operator regimes, whereas India's MDR 2017 is still expanding its oversight through guidance and MvPI.
- US vs India: Predictable statutory review clocks in the US are absent in India, where practical timelines remain variable.

Operational Impacts.

Manufacturers face tangible bottlenecks in Notified Body capacity in the EU and site audit/resource dependencies in India, while the US provides relatively predictable review timelines but still demands rigorous predicate or PMA evidence.

Strategic Implications

For manufacturers targeting multi-region submissions, the findings support several best practices:

- Early classification alignment across jurisdictions, especially for novel software/active devices.
- Integrated evidence ladders that can be modularized across submissions.
- QMS harmonization to ISO 13485 with FDA-specific deltas addressed in advance of QMSR 2026.
- Documentation crosswalks linking DHF content to 510(k)/PMA, Annex II/III TD, and India DMF/PMF.
- Proactive UDI data governance to serve both GUDID and EUDAMED.
- Resource buffers to accommodate EU NB scheduling and India's evolving infrastructure.

Limitations

The study acknowledges that jurisdictional guidance is continuously evolving, and that timelines vary by product complexity, dossier quality, and regulatory interactions. Thus, while the comparative framework is robust as of September 2025, it requires ongoing monitoring.

Closing Statement

In sum, while the US, EU, and India share a common trajectory of risk-based, lifecycle-oriented regulation, the differences in evidentiary expectations, operator responsibilities, and review timelines continue to pose strategic challenges. A harmonized, proactive approach—centered on ISO 13485, strong evidence generation, and living documentation frameworks—offers the best pathway to regulatory success, faster market access, and enhanced patient safety.

Funding

This study received no specific funding from public, commercial, or not for profit funding agencies.

AI Tool Declaration

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

Conflict of Interests

The authors declare no conflict of interest

Data Availability

Data will be available on request

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